IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ABBOTT LABORATORIES and CENTRAL GLASS CO. LTD.,	)	
Plaintiffs,	)	
	)	**04 C 0836**
v.	)	
	)	**Judge Ronald A. Guzmán**
BAXTER HEALTHCARE CORPORATION,	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

Abbott Laboratories and Central Glass Co. Ltd., the alleged owners of U.S. Patent Nos. 6,677,492 ("the '492 patent") and 6,444,859 ("the '859 patent"), have sued Baxter Healthcare Corporation for infringing those patents. The case is before the Court on plaintiffs' motion pursuant to Federal Rule of Civil Procedure Rule ("Rule") 15(a) for leave to amend their complaint and defendant's motion for leave to amend their answer. For the reasons set forth below, the Court grants plaintiffs' motion, and grants in part and denies in part defendant's motion.

Background

In 1995, Abbott, an Illinois-based healthcare company, filed a New Drug Application and received authorization from the Federal Food and Drug Administration ("FDA") to market and sell sevoflurane. (Answer ¶¶ 1-2.) Sevoflurane, which is found in Abbott's Ultane™ product, is used to induce and maintain general anesthesia in adult and pediatric

patients. (*Id.* at ¶ 1.) Abbott and Central Glass allege that they have ownership rights in both the '492 and '859 patents, which relate to sevoflurane. (*Id.* ¶¶ 8-9.)

In June 2000, Baxter, a Delaware corporation headquartered in Illinois, filed an Abbreviated New Drug Application ("ANDA") with the FDA to sell sevoflurane in the United States. (*Id.* ¶¶ 4, 10.)

In 2004, plaintiffs filed the instant suit, alleging that Baxter's efforts to market a sevoflurane product in the United States infringe both its '492 and '859 patents. (Compl. ¶ 12-13.) In response, Baxter filed an affirmative defense contending that '492 and '859 patents are invalid. (*See* Aff. Defenses ¶¶ 3-4.)

In November 2006, the Federal Circuit decided that United States Patent 5,990,176, which is the parent of the '492 and the '859 patents, was invalid as anticipated by prior art. *See Abbott Lab. v. Baxter Pharm. Prods., Inc.*, 471 F.3d 1363, 1369 (Fed. Cir. 2006).

In June 2007, plaintiffs gave Baxter a revised covenant not to sue it for infringement of the '859 patent:

> based on the importation, manufacture, use, sale, offer for sale, or any other basis for any claim of direct, contributory or induced infringement of the products that are the subject of and described in Baxter's ANDA No. 758-895, including any amendment, supplement, annual report or other change made thereto . . . or the submission of Baxter's ANDA to the Food and Drug Administration.

(Pls.' Resp. Baxter's Mot. Leave Amend Answer, Ex. A, Covenant Not To Sue at 1.)

Discussion

Motions to Amend

Plaintiff's seek to amend their complaint to, among other things, dismiss their claim for infringement of the '859 patent. Plaintiffs say the amendment is appropriate, indeed,

required, because the revised covenant not to sue eliminates the parties' controversy over the '859 patent. Baxter contends that the revised covenant does not eliminate the controversy because it does not foreclose plaintiffs from suing Baxter for infringement of the '859 patent's claims after a reissue or reexamination proceeding:

> This covenant is limited exclusively to the issued claims of the '859 patent, and does not apply to any other patent, whether related or unrelated to the '859 patent, including but not limited to any claim of any reissue patent or any reexamined patent thereof.

(Resp. Baxter Pls.' Mot. Leave Amend Compl., Ex. A, Covenant Not To Sue at 1-2.) Thus, Baxter opposes Abbott's motion and seeks to amend its answer to assert a counterclaim for a declaration that the '859 patent is invalid.

The Court agrees with Abbott. The situation in this case is similar to that in *Benitec Australia, Ltd. v. Nucleonics, Inc.*, No. 06-1122, 2007 WL 2069646 (Fed. Cir. July 20, 2007). The plaintiff in *Nucleonics* alleged that the defendant's research into applications of RNA-based gene therapy infringed its patent relating to that therapy. *Id.* at *1. After plaintiff had filed suit, the Supreme Court decided *Merck KgaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005), in which it liberally interpreted the pharmaceutical research exception to infringement. *Id.* at *1-2. Because the *Merck* decision immunized Nucleonics from infringement claims for its research activities, the plaintiff sought to dismiss its suit. *Id.* at *2. The defendant, which had asserted a counterclaim for invalidity of the patent, opposed the motion. *Id.* The district court granted the dismissal and, subsequently, plaintiff gave Nucleonics a "covenant[] . . . not to sue . . . for patent infringement arising from activities and/or products occurring on or before" the district court dismissed the suit. *Id.* (internal quotation marks omitted).

Nucleonics appealed the district court's decision, and the Federal Circuit affirmed. *Id.* at *9. A controversy is justiciable, the court said, if it is:

> "real and substantial and admit[s] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts. Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."

Id. at *3 (quoting *MedImmune, Inc. v. Genentech, Inc.*, ___ U.S.___ , 127 S. Ct. 764, 771 (2007)). Because the *Merck* decision and the covenant not to sue eliminated any present controversy between the parties, the Federal Circuit held that the dismissal was appropriate. *Id.* at *6, 9; *see Crossbow Tech., Inc. v. YH Tech.*, No. C 03-4360 SI, 2007 WL 2408879, at *6 (N.D. Cal. Aug. 21, 2007) (granting patent-holder's motion to dismiss because its covenant not to sue alleged infringer eliminated the parties' controversy).

As in *Nucleonics* and *Crossbow*, Abbott's covenant not to sue Baxter eliminates the controversy between the parties with regard to the '859 patent. Baxter's speculation that, Abbot may, at some future point, secure a reissue patent and sue on those claims does not create a *present* controversy for this Court to resolve. *See Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 856 (Fed. Cir. 1999) ("[T]he future existence of a reissue patent is wholly speculative and, therefore, cannot create a present controversy."). Because there is no current controversy with regard to the '859 patent, the Court grants plaintiff's motion to dismiss its claim for infringement of that patent.[1]

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[1]Baxter claims that plaintiffs' motion, which was filed after Baxter's motion for summary judgment on the '859 patent was fully briefed, is too late. The existence of subject matter jurisdiction, however, is an issue that can be raised at any time. *See* Fed. R. Civ. P. 12(h)(3).

Conclusion

For the foregoing reasons, the Court grants plaintiffs' motion to file an amended complaint [doc. no. 68], and grants in part and denies in part Baxter's motion for leave to file an amended answer [doc. no. 65]. Baxter is given leave to amend its answer with respect to the '492 patent, but its motion is otherwise denied. Further, the Court strikes as moot Baxter's motion for summary judgment as to the '859 patent [doc. no. 52].

SO ORDERED. **ENTERED:** 9/28/07

HON. RONALD A. GUZMAN
United States District Judge